DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 20, 2015

GlycoBioSciences Incorporated
Mr. Kevin Drizen
President
7 Timber Court
Georgetown, Ontario L7G 4S4
CANADA

Re: K143527
Trade/Device Name: IPM Wound Gel Bio/IPM Derm Gel Bio
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 16, 2015
Received: March 18, 2015

Dear Mr. Drizen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143527

Device Name
IPM Wound Gel Bio/IPM Derm Gel Bio

Indications for Use *(Describe)*

For Over-the-Counter Use:
IPM Wound Gel Bio/IPM Derm Gel Bio is indicated for management of minor burns (1st degree burns), minor abrasions, minor cuts and helps to relieve dry waxy skin irritations associated with dry skin conditions.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143527

Device Name
IPM Wound Gel Bio/IPM Derm Gel Bio

Indications for Use *(Describe)*

Prescription Use:
Under the supervision of a healthcare professional:
• IPM Wound Gel Bio/IPM Derm Gel Bio is indicated for management of exudating wounds such as leg ulcers, pressure ulcers, diabetic ulcers, surgical wounds (post-operative and donor sites), mechanically or surgically debrided wounds, and for second degree burns.
• IPM Wound Gel Bio/IPM Derm Gel Bio is indicated for the management and relief of burning, itching and pain associated with various types of dermatoses; including atopic dermatitis, allergic contact dermatitis and radio-dermatitis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the IPM Wound Gel Bio and IPM Derm Gel Bio is provided below.

Sponsor Information:

Name of 510(k) sponsor:	GlycoBioSciences Inc.
Address:	7 Timber Court Georgetown, Ontario L7G 4S4 Canada
Contact information:	Kevin Drizen, President GlycoBioSciences, Inc. 7 Timber Court Georgetown, Ontario L7G 4S4 Canada kdrizen@glycobiosciences.com Phone: 905-854-0631 Fax: 905-702-1709
Date Summary prepared:	March 14, 2015

Device Information:

Proprietary names of device:	IPM Wound Gel Bio and IPM Derm Gel Bio
Common or Usual Name:	Wound Dressing
Regulatory Class:	Unclassified
Product code:	FRO

Legally Marketed Predicate Devices:

IPM® Wound Gel Bio (K123193)
L.A.M. IPM Wound Gel and IPM Derm Gel (K130781)

No reference devices were used in this submission.

Device Description:

IPM Wound Gel Bio/IPM Derm Gel Bio is a clear viscous, odorless, aqueous gel, composed principally of sodium hyaluronate, a derivative salt of hyaluronic acid. The proportion of sodium hyaluronate "w/w" in the formulation is 2.5%.

Hyaluronic acid is a molecule which is normally found in various parts of the body. Hyaluronic acid in IPM Wound Gel Bio and IPM Derm Gel Bio is derived from a synthetic source, more specifically from a bacterial fermentation process. IPM Wound Gel Bio and IPM Derm Gel Bio serves to maintain a moist environment. The maintenance of moist environment is widely recognized to positively contribute to wound healing process. IPM Wound Gel Bio/ IPM Derm Gel Bio helps to relieve dry

waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

Other ingredients in IPM Wound Gel Bio and IPM Derm Gel Bio are as follows:
hydroxyethyl cellulose (1%), methylparaben (0.2%), as well as polyethylene glycol (3%) and purified water, USP (approx. 93%).

IPM Wound Gel Bio and IPM Derm Gel Bio are presented in the following packaging formats:
-a carton box with 4 laminated tubes of 10g (0.35oz)
-a carton box with one laminated tube of 75g (2.65oz).

IPM Wound Gel Bio and IPM Derm Gel Bio are exactly the same in all aspects and specifications; these are the same device with two (2) different trade names.

Intended Use:

IPM Wound Gel Bio and IPM Derm Gel Bio serves to maintain a moist wound environment. The maintenance of a moist wound environment is widely recognized to positively contribute to wound healing process.

IPM Wound Gel Bio and IPM Derm Gel Bio helps to relieve dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

Over-the-Counter:

IPM Wound Gel Bio/IPM Derm Gel Bio is indicated for management of minor burns (1st degree burns), minor abrasions, minor cuts and helps to relieve dry waxy irritations associated with dry skin conditions.

Rx Only:
Under the supervision of a healthcare professional;

- IPM Wound Gel Bio/IPM Derm Gel Bio is indicated for management of exudating wounds such as leg ulcers, pressure ulcers, diabetic ulcers, surgical wounds (post-operative incisions and donor sites), mechanically or surgically debrided wounds, and for second degree burns.

- IPM Wound Gel Bio/IPM Derm Gel Bio is indicated in the management and relief of burning, itching and pain associated with various types of dermatoses; including atopic dermatitis, allergic contact dermatitis and radio-dermatitis.

Device Technological Characteristics:

IPM Wound Gel Bio/IPM Derm Gel Bio is a clear viscous, odorless, aqueous gel. Hyaluronic acid is an extracellular matrix component of human skin. The Hyaluronic acid used in IPM Wound Gel Bio/IPM Derm Gel Bio is derived from a synthetic source, more specifically from a bacterial fermentation process. IPM Wound Gel Bio/IPM Derm Gel Bio serves to maintain moist wound environment. The maintenance of a moist wound environment is widely recognized to positively contribute to wound healing process.

IPM Wound Gel Bio/IPM Derm Gel Bio helps to relieve dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

The safety of IPM Wound Gel Bio/Derm Gel Bio has been already demonstrated through the Biocompatibility evaluation of its predicate IPM Wound Gel Bio. There have been no changes made to this topical formulation from the currently cleared IPM Wound Gel Bio to the proposed IPM Wound Gel Bio/Derm Gel Bio. Hence the biocompatibility tests for IPM Wound Gel Bio/Derm Gel Bio were not required to be repeated. Bio fermented HA passed biocompatibility evaluations and thus demonstrated substantial equivalence to the predicate device in this respect, i.e. biocompatibility.

Also, stability testing conducted on the predicate IPM Wound Gel Bio to support the proposed shelf-life confirmed that aged product met the acceptance criteria. Since there were no changes made to the formulation from the currently cleared IPM Wound Gel Bio to the proposed IPM Wound Gel Bio/Derm Gel Bio the stability testing are not required to be repeated for the proposed IPM Wound Gel Bio/Derm Gel Bio.

Comparison with Predicate Device:

IPM Wound Gel Bio is similar in technological characteristics and indications to the predicates (See Appendix 2A and 2B for predicates 510(k) summary) as shown in the Table below:

Proprietary Name of Device & 510(k) Number	**IPM Wound Gel Bio (K123193) (Multiple Predicate)**	**L.A.M. IPM Wound Gel and IPM Derm Gel (K130781) (Multiple Predicate)**	**IPM Wound Gel Bio and IPM Derm Gel Bio (K143527) (Proposed Device)**	**Diff-eren-ces (Yes/ No)**	**Why differences do not affect Safety &/ Performance**
Manufacturers	**GlycoBioSciences**	**GlycoBioSciences**	**GlycoBioSciences**		
Intended Use	Serves to maintain moist wound environment. The maintenance of a moist wound environment is widely recognized to positively contribute to wound healing process. Also, helps to relieve dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.	Serves to maintain moist wound environment. The maintenance of a moist wound environment is widely recognized to positively contribute to wound healing process. Also, helps to relieve dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.	Serves to maintain moist wound environment. The maintenance of a moist wound environment is widely recognized to positively contribute to wound healing process. Also, helps to relieve dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.	No	**N/A**
Indications for Use	**OTC:** IPM Wound Gel Bio is indicated for the management of minor burns (1st degree burns), minor abrasions and minor cuts and helps to relieve dry waxy skin irritations associated with dry skin conditions.	**OTC:** IPM Wound Gel Bio/ IPM Derm Gel Bio is indicated for management of minor burns (1st degree burns), minor abrasions, minor cuts and helps to relieve dry waxy skin irritations associated with dry skin conditions.	**OTC:** IPM Wound Gel Bio/ IPM Derm Gel Bio is indicated for management of minor burns (1st degree burns), minor abrasions, minor cuts and helps to relieve dry waxy skin irritations associated with dry skin conditions.	Yes	The proposed additional indications "management and relief of burning, itching and pain experienced with various types of dermatoses: including atopic dermatitis, allergic contact dermatitis and radio-dermatitis."

Proprietary Name of Device & 510(k) Number	**IPM Wound Gel Bio (K123193) (Multiple Predicate)**	**L.A.M. IPM Wound Gel and IPM Derm Gel (K130781) (Multiple Predicate)**	**IPM Wound Gel Bio and IPM Derm Gel Bio (K143527) (Proposed Device)**	**Diff-eren-ces (Yes/ No)**	**Why differences do not affect Safety &/ Performance**
	Rx Only: Under the supervision of a healthcare professional: IPM Wound Gel Bio is indicated for the management of exudating wounds such as leg ulcers, pressure ulcers, diabetic ulcers, surgical wounds (post-operative incisions and donor sites), mechanically or surgically debrided wounds, and for 2nd degree burns"	**Rx Only:** Under the supervision of a healthcare professional: • IPM Wound Gel Bio/ IPM Derm Gel Bio is indicated for management of exudating wounds such as leg ulcers, pressure ulcers, diabetic ulcers, surgical wounds (post-operative and donor sites), mechanically or surgically debrided wounds, and for second degree burns. • IPM Wound Gel Bio/IPM Derm Gel Bio is indicated in the management and relief of burning, itching and pain experienced with various types of dermatoses: including atopic dermatitis, allergic contact dermatitis and radio-dermatitis.	**Rx Only:** Under the supervision of a healthcare professional: • IPM Wound Gel Bio/ IPM Derm Gel Bio is indicated for management of exudating wounds such as leg ulcers, pressure ulcers, diabetic ulcers, surgical wounds (post-operative and donor sites), mechanically or surgically debrided wounds, and for second degree burns. • IPM Wound Gel Bio/IPM Derm Gel Bio is indicated in the management and relief of burning, itching and pain experienced with various types of dermatoses: including atopic dermatitis, allergic contact dermatitis and radio-dermatitis.		do not affect the Safety and Performance of the proposed device because maintaining a moist wound environment can provide relief of symptoms associated with dermatitis.
Device Description	Aqueous gel composed principally of sodium hyaluronate	Aqueous gel composed principally of sodium hyaluronate	Aqueous gel composed principally of sodium hyaluronate	No	N/A
Hyaluronate source	Bacterial fermentation	Avian	Bacterial fermentation	Yes	The formulation and raw material HA of the proposed device is the same as that of IPM Wound Gel Bio K123193.
Shelf Life	18 Months	18 Months	18 Months	No	

Considering that the change of indication proposed by this 510(k) only includes indications that are already approved to the predicates indicated by GlycoBioSciences, it is fair to understand that quality, safety and effectiveness are demonstrated and are comparable to the predicates.